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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/905,301	07/13/2001	Rosana Kapeller-Libermann	381552002400	6348

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MILLENNIUM PHARMACEUTICALS, INC.
40 Landsdowne Street
CAMBRIDGE, MA 02139

EXAMINER	
MOORE, WILLIAM W	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 06/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/905,301	KAPELLER-LIBERMANN, ROSANA	
	Examiner	Art Unit	
	William W. Moore	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-23 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-23 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

1. Claims 1-3 drawn in part to, and claim 6 drawn to, to a polynucleotide having a sequence that diverges as much as 40% from the coding sequence within SEQ ID NO:1, to a host cell comprising same, and to a recombinant method of making of an encoded polypeptide in a host cell comprising the polynucleotide, classified, *inter alia*, in class 536, subclass 23.2 .

2. Claims 1-3, drawn in part to an oligonucleotide having as few as fifteen consecutive nucleotides of the nucleic acid sequence of SEQ ID NO:1, classified, *inter alia*, in class 536, subclass 24.3.

3. Claim 4, drawn to a polypeptide having an amino acid sequence that may diverge entirely[1] from the amino acid sequence encoded by the coding sequence within SEQ ID NO:1, in clause (a) of the claim, or a polypeptide fragment sharing a common array of at least 15 contiguous amino acids SEQ ID NO:2, in clause (c) of the claim, or a polypeptide with the integral amino acid sequence set forth in SEQ ID NO:2, in clause (d) of the claim, classified, *inter alia*, in class 530, subclass 350.

4. Claim 5, drawn to an antibody capable of binding either to a polypeptide having an amino acid sequence that may diverge entirely from the amino acid sequence encoded by the coding sequence within SEQ ID NO:1, or a fragment of a polypeptide sharing a common array of 15 contiguous amino acids SEQ ID NO:2, or a polypeptide with the integral amino acid sequence set forth in SEQ ID NO:2, classified in class 530, subclass 387.1.

5. Claims 7 and 8, drawn in part to first method of use of an unspecified compound, which may be an oligonucleotide with a contiguous array of fifteen nucleotides of the nucleic acid sequence of SEQ ID NO:1, in an assay to detect a polynucleotide having a sequence that diverges as much as 40% from the coding sequence within SEQ ID NO:1 in a sample, and to a kit comprising same, classified in class 435, subclass 6.

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[1] 3129 nucleotides encoding a human 23430 polypeptide X 40% nonidentity = 1252 altered nucleotides. Clause (a) of claim 4 places no structural limitation on the locations of altered nucleotides, thus where alterations occur at first codon positions, 1252 altered codons may specify 1252 amino acid alterations: 1252/1043 = 1.200 ≈120%, exceeding the number of amino acids, 1043, in the sequence of the disclosed human 23430 polypeptide.

6. Claims 7 and 8, drawn in part to first method of use of an unspecified compound, which may be an antibody, in an assay to detect a polypeptide having an amino acid sequence that may diverge entirely from the amino acid sequence encoded by the coding sequence within SEQ ID NO:1, or a fragment of a polypeptide sharing a common array of 15 contiguous amino acids SEQ ID NO:2, or a polypeptide with the integral amino acid sequence set forth in SEQ ID NO:2, in a sample, classified in class 435, subclass 7.1.

7. Claim 9, drawn to a method of using a polypeptide having an amino acid sequence that may diverge entirely from the amino acid sequence encoded by the coding sequence within SEQ ID NO:1, or a polypeptide with the integral amino acid sequence set forth in SEQ ID NO:2 in an assay to detect binding by an unspecified test compound, classified in class 435, subclass 4.

8. Claim 10, drawn to a method of use of an unspecified compound to modulate the activity of a polypeptide having an amino acid sequence that may diverge entirely from the amino acid sequence encoded by the coding sequence within SEQ ID NO:1, or a polypeptide with the integral amino acid sequence set forth in SEQ ID NO:2, classified in class 436, subclass 86.

9. Claims 11, 12, 14, and 15 drawn to, and claims 21-23 drawn in part to, other methods of use of an oligonucleotide having as few as fifteen consecutive nucleotides of the nucleic acid sequence of SEQ ID NO:1, in diagnostic and prognostic assays to determine the relative representation of a polynucleotide having a sequence diverging as much as 40% from the coding sequence within SEQ ID NO:1, classified, *inter alia*, in class 436, subclass 94.

10. Claims 13 and 16 drawn to, and claims 21-23 drawn in part to, other methods of use of an antibody capable of binding to a polypeptide having the amino acid sequence set forth in SEQ ID NO:2, in diagnostic and prognostic assays to determine the relative representation of a polypeptide having an amino acid sequence that may diverge entirely from the amino acid sequence encoded by the coding sequence within SEQ ID NO:1, classified, *inter alia*, in class 435, subclass 7.4.

11. Claim 17, drawn, to a method for identifying an unspecified compound capable of treating a disorder involving the aberrant expression of a polynucleotide encoding a 23430 polypeptide, or aberrant activity of an expressed 23430 polypeptide, classified in class 436, subclass 106.

12. Claims 18-20, drawn in part to a method for treating or preventing an unspecified disorder comprising administration of a peptide or polypeptide compound capable of modulating either the expression of a polynucleotide

encoding a 23430 polypeptide or the activity of an expressed 23430 polypeptide, classified in class 514, subclass 2.

13. Claims 18-20, drawn in part to a method for treating or preventing an unspecified disorder comprising administration of a nucleic acid compound capable of modulating either the expression of a polynucleotide encoding a 23430 polypeptide or the activity of an expressed 23430 polypeptide, classified in class 514, subclass 44.

14. Claims 18-20, drawn in part to a method for treating or preventing an unspecified disorder comprising administration of a small molecule of unstated nature capable of modulating either the expression of a polynucleotide encoding a 23430 polypeptide or the activity of an expressed 23430 polypeptide, classified in class 514, subclass 1.

The inventions are distinct, each from the other, because of the following reasons:

Inventions of Groups 1 and 2 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP §806.04, MPEP §808.01). In the instant case the different inventions are not disclosed as capable of use together, nor are they disclosed to have similar modes of operation, similar functions, or effects.

Inventions of Group 1 and Group 3 are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product of Group 3 can be made by another, materially, different process, such as solid-phase chemical synthesis.

The invention of Group 1 is unrelated to inventions of Groups 4-14. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP §806.04, MPEP §808.01). In the instant case the different inventions are not disclosed as capable of use together, nor are they disclosed to have similar modes of operation, similar functions, or effects.

The invention of Group 2 is unrelated to inventions of Groups 3, 4, 6-8, 10-12 and 14. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions,

or they have different effects. (MPEP §806.04, MPEP §808.01). In the instant case the different inventions are not disclosed as capable of use together, nor are they disclosed to have similar modes of operation, similar functions, or effects.

Inventions of Groups 2 and 5 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product may be used in a materially different method of using the product, such as a diagnostic or prognostic assay.

Inventions of Groups 2 and 9 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product may be used in a materially different method of using the product, such as an assay to detect a divergent polynucleotide in a sample.

Inventions of Groups 2 and 13 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product may be used in a materially different method of using the product, such as a diagnostic or prognostic assay.

The invention of Group 3 is unrelated to inventions of Groups 4-6 and 18-14. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP §806.04, MPEP §808.01). In the instant case the different inventions are not disclosed as capable of use together, nor are they disclosed to have similar modes of operation, similar functions, or effects.

Inventions of Groups 3 and 7 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1)

the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product may be used in a materially different method of using the product, such as in the vaccination of an animal to produce an immune response.

The invention of Group 4 is unrelated to inventions of Groups 5, 7-9 and 11-14. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP §806.04, MPEP §808.01). In the instant case the different inventions are not disclosed as capable of use together, nor are they disclosed to have similar modes of operation, similar functions, or effects.

Inventions of Groups 4 and 6 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using that product, such as a diagnostic or prognostic assay.

Inventions of Groups 4 and 10 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using that product, such as such as an assay to detect a divergent polypeptide in a sample.

The invention of Group 5 is unrelated to inventions of Groups 6-14. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP §806.04, MPEP §808.01). In the instant case the different inventions are not disclosed as capable of concurrent use, nor are they disclosed to have similar modes of operation, similar functions, or effects.

The invention of Group 6 is unrelated to inventions of Groups 7-14. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP §806.04, MPEP §808.01). In the instant case the different inventions are not disclosed as capable of concurrent use, nor are they disclosed to have similar modes of operation, similar functions, or effects.

The invention of Group 7 is unrelated to inventions of Groups 8-14. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP §806.04, MPEP §808.01). In the instant case the different inventions are not disclosed as capable of concurrent use, nor are they disclosed to have similar modes of operation, similar functions, or effects.

The invention of Group 8 is unrelated to inventions of Groups 9-14. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP §806.04, MPEP §808.01). In the instant case the different inventions are not disclosed as capable of use together, nor are they disclosed to have similar modes of operation, similar functions, or effects.

The invention of Group 9 is unrelated to inventions of Groups 10-14. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP §806.04, MPEP §808.01). In the instant case the different inventions are not disclosed as capable of use together, nor are they disclosed to have similar modes of operation, similar functions, or effects.

The invention of Group 10 is unrelated to inventions of Groups 11-14. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP §806.04, MPEP §808.01). In the instant case the different inventions are not disclosed as capable of use together, nor are they disclosed to have similar modes of operation, similar functions, or effects.

The invention of Group 11 is unrelated to inventions of Groups 12-14. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together,

or they have different modes of operation, or they have different functions, or they have different effects. (MPEP §806.04, MPEP §808.01). In the instant case the different inventions are not disclosed as capable of use together, nor are they disclosed to have similar modes of operation, similar functions, or effects.

The invention of Group 12 is unrelated to inventions of Groups 13 and 14. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP §806.04, MPEP §808.01). In the instant case the different inventions are not disclosed as capable of use together, nor are they disclosed to have similar modes of operation.

Inventions of Groups 13 and 14 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP §806.04, MPEP §808.01). In the instant case the different inventions are not disclosed as capable of use together, nor are they disclosed to have similar modes of operation.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR §1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR §1.48(b) and by the fee required under 37 CFR §1.17(h).

A telephone call was made to Mr. Mario Cloutier on June 22, 2004, to request an oral election to the above restriction requirement, but did not result in an election being made.

Notice of Requirements for Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier.** Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. §§101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. §121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William W. Moore whose telephone number is now 571.272.0933. The examiner can normally be reached between 9:00AM and 5:30PM EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can now be reached at 571.272.0928. The fax phone numbers for all communications for the organization where this application or proceeding is assigned remains 703.872.9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is now 571.272.1600.

William W. Moore
June 22, 2004

PONNATHAPU ACHUTAMURTHY
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600